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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,176	03/19/2007	Irun R. Cohen	85189-10700	4023

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PATENT DEPARTMENT
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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
09/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/580,176	COHEN ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-128* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *91-128* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed May 22, 2006 has been entered. Claims 1-90 have been cancelled and Claims 91-128 have been newly added.

Accordingly, Claims 91-128 are pending in the instant application.

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 91-105, drawn to (1) a DNA vaccine comprising a recombinant construct comprising a nucleic acid sequence encoding a fragment of heat shock protein 60 (HSP60) characterized in that it reacts with T cells isolated from an animal vaccinated with HSP70 to induce Th2/3 T cell responses, (2) a recombinant construct, and (3) a pharmaceutical composition.

Group II, Claims 106-108, drawn to a pharmaceutical composition comprising a peptide fragment of HSP60 that reacts with T cells isolated from an animal vaccinated with HSP70 to induce Th2/3 T-cell responses.

Group III, Claims 109-117, drawn to a method of treating or preventing the symptoms of a T cell-mediated inflammatory autoimmune disease, comprising administering to a subject in need thereof a therapeutically effective amount of a pharmaceutical composition comprising a recombinant construct comprising a nucleic acid sequence encoding a fragment of HSP60.

Group IV, Claims 118-121, drawn to a method for treating or preventing the symptoms of a T cell-mediated inflammatory autoimmune disease comprising the steps of (a) obtaining cells from a subject; (b) transfecting the cells *in vitro* with a recombinant construct (or infecting the cells *in vitro* with a virus comprising a recombinant construct); and (c) reintroducing the transfected cells to the subject, thereby treating the disease.

Group V, Claim 128, drawn to a method of screening for active fragments of HSP60 capable of inducing Th2/3 T cell responses.

Claims 122-127 cannot be placed into a restriction group because Claim 122 depends from Claim 16 which has been cancelled. Accordingly, the composition being administered is undefined. A **clarifying amendment is required** so that the claims may be placed into an appropriate restriction group.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons.

The technical feature linking Groups I-V is the peptide fragment of HSP60. However, the technical feature does not rise to the level of a special technical feature because HSP60, particularly human HSP60, as well as peptide fragments of HSP60 were known in the prior art. See for example, Abulafia-Lapid et al. (1999, J. Autoimmun. 12(2): 121-129) which discloses peptides of human HSP60 and T cell proliferative responses to the peptides. The reference further discloses that newly diagnosed type 1 diabetes patients show heightened autoimmunity to hsp60 and hsp60 peptides.

Accordingly, Groups I-V are not so linked by the same or corresponding special technical feature as to form a single general inventive concept.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of

the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

Part 1. Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following distinct peptide fragments, as set forth in the claims:

A. amino acids 271-290 of human HSP60 (SEQ ID NO: 1)

B. amino acids 346-365 of human HSP60 (SEQ ID NO: 2)

C. amino acids 361-380 of human HSP60 (SEQ ID NO: 3)

D. amino acids 391-410 of human HSP60 (SEQ ID NO: 4)

E. amino acids 406-425 of human HSP60 (SEQ ID NO: 5)

F. amino acids 436-455 of human HSP60 (SEQ ID NO: 6)

G. amino acids 466-485 of human HSP60 (SEQ ID NO: 7)

H. amino acids 481-500 of human HSP60 (SEQ ID NO: 8)

I. amino acids 496-515 of human HSP60 (SEQ ID NO: 9)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 91, 97, 101, 106, 109, 118, 120, and 122 are generic.

Part 2. Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following distinct transcription control sequences, as set forth in the claims:

A. RSV control sequences

B. CMV control sequences

C. retroviral LTR sequences

D. SV40 control sequences

E. β-actin control sequences

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 91, 97, 101, 109, 118 and 120 are generic.

Part 3. Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following distinct eukaryotic expression vectors, as set forth in the claims:

A. pcDNA3

B. pcDNA3.1(+/-)

C. pZeoSV2(+/-)

D. pSecTag2

E. pDisplay

F. pEF/myc/cyto

G. pCMV/myc/cyto

H. pCR3.1

I. pCI

J. pBK-RSV

K. pBK-CMV

L. pTRES

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 97 is generic.

Part 4. Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following distinct delivery vehicles, as set forth in the claims:

A. liposomes

B. micelles

C. emulsions

D. cells

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 101 is generic.

Part 5. Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following distinct T cell-mediated inflammatory autoimmune disease, as set forth in the claims:

A. rheumatoid arthritis

B. collagen II arthritis

C. multiple sclerosis

D. autoimmune neuritis

E. systemic lupus erthematosus

F. psoriasis

G. juvenile onset diabetes

H. Sjogren's disease

I. thyroid disease

J. sarcoidosis

K. autoimmune uveitis

L. inflammatory bowel disease (Crohn's and ulcerative colitis)

M. autoimmune hepatitis

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 109 and 122 are generic.

Part 6. Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following distinct modes of administration, as set forth in the claims:

A. intravenous injection

B. intramuscular injection

C. aerosol

D. oral

E. percutaneous

F. topical administration

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 109 and 122 are generic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species associated with the elected invention, even though this requirement is traversed.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim

will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet.

The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/
Primary Examiner, Art Unit 1632